04-651

CBR PROJECT ARRANGEMENT NO. CA-US-A-00-0001

BETWEEN

THE

SECRETARY OF DEFENSE ON BEHALF OF
THE DEPARTMENT OF DEFENSE OF THE UNITED STATES OF AMERICA

AND THE

DEPARTMENT OF NATIONAL DEFENCE OF CANADA

CONCERNING

A SMALLPOX (SP) VACCINE SYSTEM DEVELOPMENT PROGRAM
(SPVSDP)

TABLE OF CONTENTS

SECTION		PAGE
I	INTRODUCTION	3
II	DEFINITION OF TERMS AND ABBREVIATIONS	3
III	OBJECTIVE	4
IV	SCOPE OF WORK	4
V	SHARING OF TASKS	5
VI	BREAK DOWN AND SCHEDULE OF TASKS	6
VII	MANAGEMENT	6
VIII	FINANCIAL ARRANGEMENTS	7
IX	SPECIAL PROVISIONS	8
X	CONTRACTING	9
XI	LEVEL OF CLASSIFICATION	9
XII	PRINCIPAL ORGANIZATIONS INVOLVED	9
XIII	EQUIPMENT AND MATERIAL TRANSFERS	10
XIV	ENTRY INTO EFFECT, DURATION AND TERMINATION	12

SECTION I
INTRODUCTION

1.1 This Smallpox Vaccine System Development Program Project Arrangement (SPVSDP PA) is entered into pursuant to the Memorandum of Understanding between the Department of National Defence of Canada, the Secretary of State for Defence of the United Kingdom of Great Britain and Northern Ireland, and the Secretary of Defense on behalf of the Department of Defense of the United States of America, concerning the Research, Development and Acquisition of Chemical, Biological and Radiological Defense Material of June 1, 2000, the provisions of which are hereby incorporated by reference.

1.2 The Contributing Participants to this SPVSDP PA are the Secretary of Defense on behalf of the Department of Defense of the United States of America and the Department of National Defence of Canada.

SECTION II
DEFINITION OF TERMS AND ABBREVIATIONS

2.1 For the purposes of this SPVSDP PA, the following are defined:

IND	Investigational New Drug.
IPT	Integrated Product Team. A team composed of representatives from appropriate functional disciplines working together to build a successful and balanced acquisition program. It provides technical oversight and programmatic recommendations for research, development and acquisition.
JVAP	U.S. Joint Vaccine Acquisition Program.
Licensure	The final approval of a product for defined indications by a national regulatory agency based upon evaluation of data and processes collected during vaccine development that validate product safety and efficacy.
SP Vaccine System	The products and efforts needed to deliver a Smallpox Vaccine capability, including Smallpox Vaccine, appropriate product labeling and package inserts, delivery system, Vaccinia Immune Globulin, and education/training/communication support material.

SECTION III
OBJECTIVE

3.1 The objective of this SPVSDP PA is to develop jointly a licensed SP Vaccine System that meets the requirements of the Contributing Participants.

3.2 To meet this objective, the Contributing Participants will:

3.2.1 Participate in the JVAP SP Vaccine System advanced development program.

3.2.2 Generate and assemble a data package(s) to support Licensure of the SP Vaccine System in each country.

SECTION IV
SCOPE OF WORK

4.1 The following work will be carried out under this SPVSDP PA:

4.1.1 Integration of national requirements into the JVAP SP Vaccine System advanced development program.

4.1.2 Development and Licensure activities for a SP Vaccine System.

4.1.2.1 Manufacture consistency lots that are sufficient to immunize for the U.S. DoD 300K individuals, and for CA DND 58.5K individuals.

4.1.2.2 Conduct clinical trials.

4.1.2.3 Prepare and submit Licensure applications and obtain Licensure.

4.1.2.4 Deliver consistency lots as final packaged products, as specified in paragraph 4.1.2.1 or at a ratio of U.S. DoD – 83.7%, CA DND – 16.3%, whichever is greater.

4.1.3 Development of training materials (brochures, tapes, etc.) with information on SP Vaccine System to educate users and recipients.

4.1.4 Development of a post-licensing plan to ensure the SP Vaccine System remains licensed.

4.1.5 Development of a post-licensing plan for a production capability.

SECTION V
SHARING OF TASKS

5.1 The sharing of tasks will be as follows:

5.1.1 The U.S. DoD will:

5.1.1.1 Provide subject matter expertise in the development of the SP Vaccine System.

5.1.1.2 Establish and chair the SP Vaccine System IPT, with CA DND participation as a voting member.

5.1.1.3 Contract on behalf of Contributing Participants for the development and Licensure of the SP Vaccine System.

5.1.1.4 Obligate and manage funds provided from the Contributing Participants for execution of the SPVSDP.

5.1.1.5 Provide information packages for the SP Vaccine System suitable for users such as vaccine recipients, health care providers, and commanders.

5.1.1.6 Provide, upon request, product data to support a CA DND IND application, and 16.3% of available consistency lot material as IND products.

5.1.1.7 Deliver consistency lots in accordance with paragraph 4.1.2.4.

5.1.1.8 Provide or fund unique U.S. DoD requirements.

5.1.2 The CA DND will:

5.1.2.1 Provide subject matter expertise in the development of the SP Vaccine System.

5.1.2.2 Participate as a voting member in the SP Vaccine System IPT and participate in the IPT process.

5.1.2.3 Provide or fund unique CA DND requirements.

5.1.3 The U.S. DoD and the CA DND will jointly:

5.1.3.1 Manage critical decision points as outlined in Section VI (Break Down and Schedule of Tasks).

5.1.3.2 Develop requirements for information packages for the SP Vaccine System suitable for users, such as vaccine recipients, health care providers, and commanders.

5.1.3.3 Develop a post-licensing plan to ensure the SP Vaccine System remains licensed.

5.1.3.4 Develop a post-licensing plan for a production capability.

SECTION VI
BREAK DOWN AND SCHEDULE OF TASKS

6.1 This Project will proceed according to the following phases and schedule. These tasks are sequential and represent critical decision points for this SPVSDP PA.

Phase	Start	End
Modify contract	Y1	Y1
File IND application for clinical trials	Y1	Y1
Manufacture SP Vaccine System consistency lots	Y1	Y1
Conduct clinical trials	Y2	Y4
Prepare and submit Licensure applications	Y4	Y5
Licensure	Y5	Y6
Deliver SP Vaccine System	Y6	Y6
Prepare and deliver of final report	Y7	Y7

SECTION VII
MANAGEMENT

7.1 The TOs for this SPVSDP PA will be:

7.1.1 U.S. DoD TO

Title/Position	JVAP SP Vaccine System Manager
Organization	Joint Vaccine Acquisition Program
Address	1436 Porter St. Ft. Detrick, MD 21702-5041

7.1.2 CA DND TO

Title/Position	Canadian Forces Medical Group Assistant Chief Of Staff Operations – Operational Medicine
Organization	National Defence Headquarters
Address	1745 Alta Vista Drive Ottawa ON CANADA K1A 0K6

7.2 The TOs will designate their members to the SP Vaccine System IPT.

SECTION VIII
FINANCIAL ARRANGEMENTS

8.1 The Contributing Participants estimate that performance of work under this SPVSDP PA will not exceed 172 person-months of effort.

8.1.1 The estimated U.S. DoD contribution is 72 person-months.

8.1.2 The estimated CA DND contribution is 100 person-months.

8.2 The Contributing Participants estimate that the total cost of the contracted effort under this SPVSDP PA will be U.S. $55.4M. The Contributing Participants will provide funding as follows:

8.2.1 The U.S. DoD contribution will be 83.7% of the contract cost, not to exceed U.S. $46.2M.

8.2.2 The CA DND contribution will be 16.3% of the contract cost, not to exceed U.S. $9.2M.

8.2.3 Any unique national requirement not already included in the scope of this SPSVDP will be funded by the Contributing Participant with the additional unique national requirement.

8.3 In accordance with Section VI (Financial Provisions) of the CBR MOU, the TOs will prepare a financial management procedures document.

8.4 Cooperative efforts of the Contributing Participants not included within Section III (Objective), Section IV (Scope of Work), Section V (Sharing of Tasks), or Section VIII (Financial Arrangements) will require amendment to this SPVSDP PA or execution of a new CBR PA.

SECTION IX
SPECIAL PROVISIONS

9.1 Liability and Claims.

9.1.1 Pursuant to paragraph 5.1.1.3 of this SPVSDP PA, the U.S. Army Medical Research Acquisition Activity contracted with DynPort LLC (DVC) to perform work to satisfy Section III (Objective) and Section IV (Scope of Work) of this SPVSDP PA. Under this contract, the U.S. Army has agreed to indemnify DVC against unusually hazardous activities as specified under the contract. The Contributing Participants will share the cost of any liability related to the development or Licensure of the SP Vaccine System in accordance with paragraph 14.2 of the CBR MOU.

9.1.2 Notwithstanding paragraph 9.1.1:

9.1.2.1 The shared liability will not apply to claims or causes of actions arising from use by a Contributing Participant of the SP Vaccine System as an IND (excluding clinical trials required for Licensure) or after Licensure. Each Contributing Participant will then be solely liable for any contract claims or causes of action arising from such use.

9.1.2.2 Any liability arising in connection with unique national requirements will be borne entirely by that Contributing Participant.

9.1.3 The Contributing Participants will notify each other of all claims or actions arising under this SPVSDP PA in a timely manner and consult with one another regarding such claims or actions.

9.1.4 The respective rights and responsibilities of the Contributing Participants regarding the liability and claims provisions of this SPVSDP PA will continue notwithstanding termination or expiration of this SPVSDP PA and/or the CBR MOU.

9.2 Background Information.

9.2.1 Government Background Information: Government Background Information disclosed by one Contributing Participant may be used without charge by or for the other Contributing Participant only for conducting this SPVSDP PA. The disclosing Participant will retain all its rights with respect to such Government Background Information.

9.2.2 Contractor Background Information: Contractor Background Information disclosed by one Contributing Participant may be used without charge by or for the other Contributing Participant only for conducting this SPVSDP PA. The disclosing Participant will retain all its rights with respect to such Contractor Background Information. Such Background Information may be the subject of further restrictions of proprietary rights.

9.2.3 Notwithstanding the provisions of 9.2.1 and 9.2.2, Background Information embedded in Foreground Information will be provided for Defense Purposes.

9.3. To ensure future interoperability of the SP Vaccine System between the Contributing Participants (that is, vaccine licensable in both countries), the U.S. DoD will use its best efforts to assist the CA DND in establishing a production capability through separate arrangements that address, but are not limited to, providing SP Vaccine seed stock and necessary cell lines.

SECTION X
CONTRACTING

10.1 For the purposes of this SPVSDP PA, the U.S. DoD will contract on behalf of, but not as an agent for, the CA DND.

10.2 The U.S. DoD contract will be amended to include the requirement for:

10.2.1 The preparation and submission of license applications to Health Canada for all licensable components of the SP Vaccine System.

10.2.2 Delivery to CA DND of the SP Vaccine System.

10.3 Any other unique national CA DND requirement will be subject to a separate contract amendment.

SECTION XI
LEVEL OF CLASSIFICATION

11.1 The highest level of Classified Information or Materiel, which may be exchanged under this SPVSDP PA is CONFIDENTIAL.

SECTION XII
PRINCIPAL ORGANIZATIONS INVOLVED

12.1 For the U.S. DoD:

12.1.1 Joint Vaccine Acquisition Program Project Management Office
1436 Porter Street
Ft. Detrick, MD 21702-5041

12.1.2 Joint Program Office for Biological Defense
5203 Leesburg Pike, Suite 1609, Skyline #2
Falls Church, VA 22041-3203

12.1.3 United States Army Medical Research and Materiel Command
Ft. Detrick, MD 21702-5000

12.1.4 United States Army Medical Research Institute of Infectious Diseases
Ft. Detrick, MD 21702-5011

12.1.5 United States Army Space and Missile Defense Command
Chemical and Biological Agent Branch (SMDC-CM-CBA)
Joint Vaccine Acquisition Program Project Office
1436 Porter Street
Fort Detrick, MD 21702-5041

12.2 For the CA DND:

12.2.1 National Defence Headquarters
101 Colonel By Drive
Ottawa, ON
K1A OK2

12.2.2 Defence R&D Canada
305 Rideau Street
Ottawa, ON
K1A OK2

SECTION XIII
EQUIPMENT AND MATERIAL TRANSFERS

13.1 The loan and/or transfer of the following Equipment and Material is necessary for executing this SPVSDP PA. Equipment and Material is loaned or transferred only for the purposes set forth in Section III (Objective) and Section IV (Scope of Work) of this SPVSDP PA.

13.2 The following Equipment and Material may be transferred by the providing Participant to the receiving Participant under this SPVSDP PA for the purposes of test and evaluation:

Providing Participant	Receiving Participant	Quantity	Description	Stock Number	Approx Value	Classification of Item
U.S. DoD	CA DND	10 vials	SP Vaccine Seed Stock	N/A	US $10,000	UNCLASS
CA DND	U.S. DoD	1000 doses	Smallpox Vaccine (Connaught)	N/A	US $10,000	UNCLASS
U.S. DoD	CA DND	1000 doses	Interim SP Vaccine System	N/A	US $10,000	UNCLASS

13.3 Transfer of the Equipment and Material - The providing Participant will transfer the Equipment and Material listed above for a one-year period unless extended by mutual written consent.

13.4 Equipment and Material Delivery - The providing Participant will make available the Equipment and Material at a to-be-designated U.S. site. Custody of the Equipment and Material will pass from the providing Participant to the receiving Participant at the time of receipt of the Equipment and Material. Any further transportation is the responsibility of the receiving Participant in accordance with applicable laws and regulations.

13.5 Consumption of Equipment and Material - It is intended that the receiving Participant will consume the Equipment and Material specified in paragraph 13.2 during the course of the activity described in Section IV (Scope of Work). If this does occur, the receiving Participant will provide written notice of its consumption to the providing Participant. In the event consumption does not occur prior to the end of this SPVSDP PA as specified in Section XIV (Entry into Effect, Duration and Termination), the receiving Participant will destroy the Equipment and Material. The receiving Participant will issue a certificate of loss/destruction/irreparable damage to the providing Participant as applicable.

SECTION XIV
ENTRY INTO EFFECT, DURATION AND TERMINATION

This Smallpox Vaccine System Development Program PA will enter into effect upon its signature, and will remain in effect for 7 years unless terminated by the Contributing Participants. It may be extended only with written consent of the Contributing Participants.

FOR THE U.S. DoD

Signature _____

Name Stephen V. Reeves

Title Joint Program Manager for Biological Defense

Date 27 March 2002

Location Falls Church, Virginia, USA

FOR THE CA DND

Signature _____

Name L.J. Leggat

Title Assistant Deputy Minister (Science & Technology)

Date 14 March 2002

Location Ottawa, Ontario, Canada